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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,230	06/21/2005	David L. Reynolds	12916-82	1625

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EXAMINER	
WIEST, PHILIP R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
07/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,230	REYNOLDS, DAVID L.	
	Examiner	Art Unit	
	Philip R. Wiest	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-24 and 29-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11-24 and 29-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 June 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/24/09 has been entered.

Response to Amendment

In the reply filed 4/24/09, applicant amended claim 1. Claims 1-9, 11-24, and 29-45 are currently pending.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 2, 11, 14, 21, 29, 30, 37, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Genese (US 4,180,070) in view of Arnissolle (US 6,746,438).

3. With respect to Claims 1 and 29, Genese discloses an assembly for transferring fluid between a vessel having a piston inserted at an open end thereof and a vial comprising a housing having first and second ends and a bore extending therethrough, the piston being removably connected to the housing. A conduit having first and second apertures is longitudinally slidable within the bore between a retracted position (Figure 1) and an activated position (Figures 2-3). The device further comprises a vial socket assembly having a vial socket for receiving a vial, a vessel socket assembly for receiving the vessel, and a hollow piercing member for piercing the vial, said vial socket assembly moveable longitudinally relative to the housing with the housing. The second end of the conduit is fully capable of being releasably connected to the vial socket assembly. Advancing the vial socket assembly longitudinally toward the housing advances the conduit from the retracted position to the activated position to fluidly connect the vessel and the vial. See Figures 1-3. Genese, however, does not specifically teach that the vessel has a reduced-diameter neck at the closed end thereof.

Arnissolle teaches a fluid transfer device comprising a vessel having a moveable piston disposed therein and a vial having a penetrable seal, wherein fluid is transferred from the vessel to the vial via a tubular piercing member. The vessel has a neck portion opposite the open end, such that a cover member can engage the neck so as to allow for the vessel to be moved axially with respect to the adapter body (Column 5, Lines 16-36 and Figures 1-2). Upon axial displacement of the vessel in direction F4 (Figure 4), the hub and piston move relative to the adapter body until the hollow needle establishes

fluid communication with the vessel 12 and the vial 14, thereby transferring fluid from the vessel to the vial (see Figures 4-6). Once fluid transfer is complete and the medicaments are mixed, the vessel is pulled outward from the adapter body (in direction F7 - see Figure 7) so as to cause the fluid mixture to return to the vessel. Therefore, by providing a narrow neck on the closed end of the vessel, a cover means may be attached thereto, thereby improving the movability of the vessel with respect to the adapter body. Genese's device comprises a vessel that moves axially toward the adapter body to transfer fluid to the vessel (See Genese; Figures 1-4), then is moved axially away from the adapter body to transfer fluid back to the vessel (Figure 5). Genese's vessel, however, must be manually gripped to be moved between the first and second axial positions. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the fluid transfer device of Genese with Arnissolle's vessel having a reduced-diameter neck, such that the vessel may be easily moved between two axial positions by attaching a large gripping surface to the neck.

4. With respect to Claims 2, 11, 14, 21, 30, 37, and 39, Genese teaches that the first end of the conduit has a piercing member and the conduit has an aperture at the tip that extends through the conduit. The interior of the vial socket is a retaining member. The vessel may be a syringe or a cartridge. Genese teaches that the vessel may be either a cartridge or a syringe, such that the a hollow needle may be attached thereto.

5. Claims 1-4, 9, 11-13, 21, 29-32, 37, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haber et al. (US 5,393,497) in view of Genese, and further in view of Arnissolle.

6. With respect to Claims 1 and 29, Haber discloses an assembly for transferring fluid between a vessel and a vial comprising a housing 2 having first and second ends and a bore (22, 90) extending therethrough, and a slidable piston (between spaces 90 and 104 in Figure 3) removably connected to the housing. A conduit (110, 53) having first and second apertures is longitudinally slidable within the bore between a retracted position in which the first aperture (above the piston in figure 3) is positioned within the housing and connected to the piston, and an activated position in which the first aperture protrudes into the body of a vessel 10 that is attached to the housing. The device further comprises a vial socket assembly (48, 58) having a vial socket (48, 58) for receiving a vial, and a hollow piercing member 53 for piercing the vial, said vial socket assembly moveable longitudinally relative to the housing with the housing. The second end of the conduit is releasably connected to the vial socket assembly. Advancing the vial socket assembly longitudinally toward the housing advances the conduit from the retracted position to the activated position to fluidly connect the vessel and the vial. Haber, however, does not specifically disclose that the slidable piston is located within the vessel, nor does Haber teach that the vessel comprises a reduced-diameter neck portion opposite the open end.

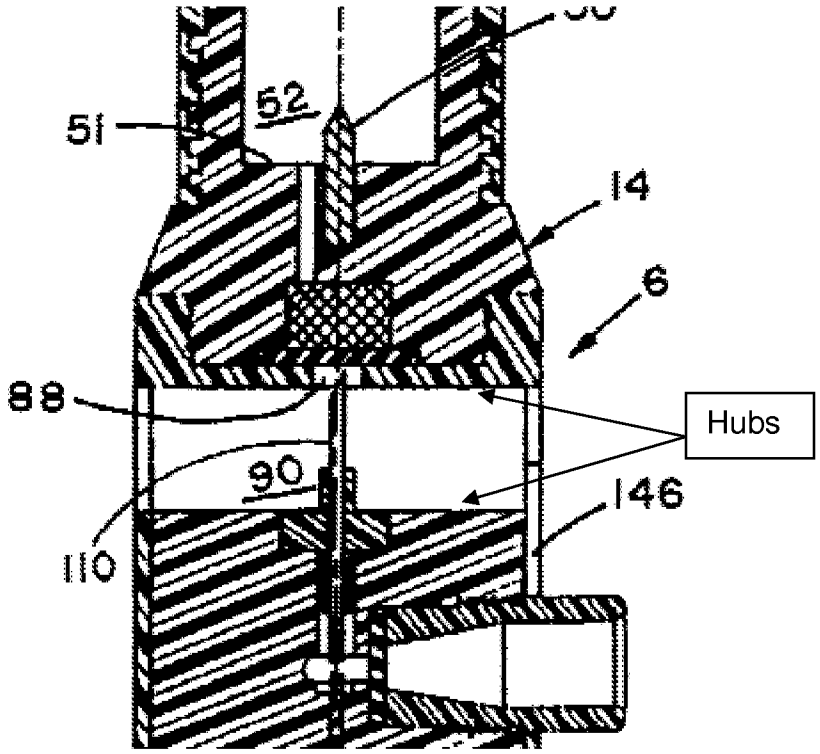
Regarding Haber's failure to teach that the piston is disposed within the vessel, Genese discloses a fluid transfer assembly for transferring fluids between a vessel and

a vial comprising a vessel having a piston disposed therein. The vessel and piston are capable of moving relative to the assembly, thereby allowing the conduit to puncture the piston and create fluid communication between the vessel and the vial. When the piston moves, a pressure difference is created within the vessel and vial, such that fluid transfer occurs (see Figures 1-5). Additionally, by locating the piston within the vessel, a seal is created, thereby preventing fluids from exiting the vessel except through the conduit (see Figures 1-3). The use of pistons to transfer medical fluids between vessels is extremely common in the medical art because it allows fluids to be transferred easily by imparting axial motion on the transfer device. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the transfer device of Haber with the piston enclosed in the vessel of Genese in order to provide a moveable sealing means that allows fluid to be transferred through the conduit when the device is advanced to the second position.

Haber and Genese, however, do not teach or suggest that the vessel has a reduced-diameter neck portion opposite the open end of the vessel. Arnissolle teaches a fluid transfer device comprising a vessel having a moveable piston disposed therein and a vial having a penetrable seal, wherein fluid is transferred from the vessel to the vial via a tubular piercing member. The vessel has a neck portion opposite the open end, such that a cover member can engage the neck so as to allow for the vessel to be moved axially with respect to the adapter body (Column 5, Lines 16-36 and Figures 1-2). Upon axial displacement of the vessel in direction F4 (Figure 4), the hub and piston move relative to the adapter body until the hollow needle establishes fluid

communication between the vessel 12 and the vial 14, thereby transferring fluid between the vessel and the vial (see Figures 4-6). Once fluid transfer is complete and the medicaments are mixed, the vessel is pulled outward from the adapter body (in direction F7 - see Figure 7) so as to cause the fluid mixture to return to the vessel. Therefore, by providing a narrow neck on the closed end of the vessel, a cover means may be attached thereto, thereby improving the movability of the vessel with respect to the adapter body. Genese's device comprises a vessel that moves axially toward the adapter body to transfer fluid to the vessel (See Genese; Figures 1-4), then is moved axially away from the adapter body to transfer fluid back to the vessel (Figure 5). Genese's vessel, however, must be manually gripped to be moved between the first and second axial positions. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the fluid transfer device of Haber and Genese with Arnissolle's vessel having a reduced-diameter neck, such that the vessel may be easily moved between two axial positions by attaching a large gripping surface to the neck.

7. With respect to Claims 2, 3, 30, and 31, Haber teaches the first end of the conduit has a piercing member that pierces the vessel, and the aperture is an opening adjacent the tip of the piercing member. A plurality of hubs are also disposed in the housing:



8. With respect to Claims 4 and 32, Haber teaches that the vial socket assembly comprises a post for receiving the second end of the conduit. Because the structural specifics of the post are not defined, a "post" may be any structure that receives the second end of the conduit.

9. With respect to claim 9, Haber discloses an aperture on the sidewall of the conduit having a blunt end.

10. With respect to Claims 11-13, 37, and 38, Haber teaches that the vial socket assembly 58 comprises a retaining member (30, 60) in the vial socket for retaining a vial 8 within the vial socket. The retaining member further comprises a plurality of retaining latches (40, 44). The retaining member 30 gets narrower near the top (above the retaining latches (40, 44), therefore forming an annular ridge with a smaller inner diameter than the surrounding area.

11. With respect to Claim 21, Haber discloses that the vessel is a cartridge (a "cartridge" may be of any shape) having a neck with a penetrable closure and a cap to retain the closure thereon.

12. Claims 4-6, 14, 32-34, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haber in view of Genese and Arnissolle, and further in view of Safabash (US 6,253,804).

13. With respect to Claims 4-6 and 32-34, Haber, Genese, and Arnissolle reasonably suggest the device substantially as claimed (see rejection above), and further disclose that the bore of the housing has a first portion, a second portion, and a shoulder disposed therebetween. Haber, Genese, and Arnissolle, however, do not specifically disclose that the post and hub form a luer connector. Safabash discloses a fluid transfer container system comprising a first container, a second container, and a piston hub 10 disposed therebetween (see figure 1). The containers may be connected to the hub by luer connectors 74 (see Figure 11) to ensure a safe, secure fit (Column 7, Lines 35-39). Luer connectors are extremely well known in the medical fluid transfer art for this very reason. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the fluid transfer system of Haber, Genese, and Arnissolle with the Luer connector of Safabash in order to improve the quality of the seal between containers during medical fluid transfer, thereby ensuring sterility of the fluid.

14. With respect to Claims 14 and 39, Haber, Genese, and Arnissolle reasonably suggest the device substantially as claimed, but do not specifically state that the vessel is a syringe. Safabash discloses a fluid transfer device comprising a syringe that is

attached to a piston hub 10. The syringe comprises a neck 34 with a flanged head portion disposed thereon. Furthermore, the syringe is positioned such that capable of being pierced by a needle to establish fluid communication. This type of fluid transfer is well established in the art. Therefore, it would have been obvious to one of ordinary skill in the art to replace the first vessel of Haber, Genese, and Arnissolle with a syringe in order to allow for fluid transfer from a different type of container. Additionally, the use of a syringe allows for control (via the piston 40) over the rate at which fluid is dispensed.

15. Claims 7, 8, 35, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haber in view of Genese, Arnissolle, and Safabash, and further in view of Haining (US 5,527,306). Haber, Genese, Arnissolle, and Safabash disclose the device substantially as claimed (see rejection above), but do not specifically disclose the use of springs as a biasing members for the conduit. Haining discloses a vial adapter comprising a spring that surrounds a valve stem and provides an upward force to bias the seat from an open to a closed position (Column 2, Lines 61-67). Springs provide an inexpensive, effective biasing member for improving the functionality of moving parts of a fluid flow device. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Haber, Genese, Arnissolle and Safabash with the resilient biasing spring of Haining in order to cause the device to return to the retracted position quickly and easily, thereby reducing the amount of effort required to operate the device.

16. Claims 15-24 and 40-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haber in view of Genese, Arnissolle, and Safabash, and further in view or Koller (US 2004/0260248). Haber, Genese, Arnissolle, and Safabash disclose the device of claim 14 substantially as claimed, but do not disclose that the device further comprises a piston backstop device. Koller discloses a medicinal syringe having a piston stopper means that is shaped and sized to receive a housing, and removably connected to the flange of the syringe. Piston backstops are well established in the art of medical fluid transfer devices because they prevent unintentional withdraw of the piston element from the bore and prevent the device from being reused [0027]. Therefore, it would have been obvious to one of ordinary skill in the art to modify the fluid transfer device of Haber, Genese, Arnissolle, and Safabash with the piston stopper of Koller in order to prevent the piston element from being removed from the bore, and to prevent the device from being reused.

17. With respect to Claim 18, Haber discloses that the vessel is a glass container. Glass syringes are also well established in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to substitute a plastic syringe for a glass syringe because the selection of a known material based on its suitability for its intended use does not constitute a patentable improvement over the prior art. See MPEP § 2144.07.

18. With respect to Claims 20, 24, and 44, Haber in view of Genese, Arnissolle Safabash and Koller disclose the device substantially as claimed, but do not specifically

disclose that the piston backstop is integrally molded to the vessel. However, the use of a one-piece construction instead of the structure disclosed in the prior art would merely a matter of obvious engineering choice. See MPEP § 2144.04. Therefore, it would have been within the scope of one of ordinary skill in the art at the time of invention to integrate the vessel and the piston backstop in order to simplify the device and prevent reuse of the fluid transfer device. Additionally, the devices of Haber and Genese are fully capable of being used with a plastic vessel. Plastic vessels are extremely common in the art of medical fluid handling.

Response to Arguments

Applicant's arguments filed 4/24/09 have been fully considered but they are not persuasive.

Regarding Genese's lack of a reduced-diameter neck portion, applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Applicant also argues that Genese does not teach that the housing is removably connectable to the piston through the open end of the vessel. This argument has not been found persuasive. Genese teaches a central housing having pistons (20, 31) disposed at either end so as to close off the vessel and the vial. The pistons are axially slidable so as to allow fluid to be transferred between the vessel and the vial. The pistons are fully capable of being removed from the housing assembly.

Applicant also argues that the cannula of the prior art is not longitudinally slidable within the bore of the housing. This argument has not been found persuasive.

Genese's cannula 23 is disposed on a hub 25 that moves axially with respect to the bore of the housing. Therefore, both the hub and the housing are slidable within the bore. Haber also teaches a cannula that is attached to the piston and moves through the bore to establish fluid communication.

Finally, applicant argues that Haber does not teach or suggest a slidable piston within the vessel, nor does Haber disclose a piston at all. As discussed in the rejection above, Haber teaches a piston (146, 92) that slides axially in order to establish fluid communication with vessel 10. Although Haber's piston is not disposed in the vessel, Genese provides clear motivation to place such a piston within a vessel or a vial. By placing a piston within a vessel, fluids can be transferred between vessels by moving the piston between a first and second position, thereby creating a pressure differential (see Figures 1-5 of Genese).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phil Wiest/
Examiner, Art Unit 3761

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
16 July 09